

In the United States Court of Federal Claims

No. 06-435V

(Filed Under Seal: March 8, 2013)

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CYNTHIA LA LONDE, parent of M.L., a *
minor, *

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Vaccine Act; Motion for Review; DTaP
Vaccine; Anaphylactic Reaction; Focal
Brain Injury; Neurological Injuries; Althen;
Causation-in-Fact; Consideration of
Petitioner's Affidavit; Expert Credibility;
Consideration of Evidence Deemed
Irrelevant

Ronald C. Homer and Joseph M. Pepper, Boston, MA, for petitioner.

Linda S. Renzi, United States Department of Justice, Washington, DC, for respondent.

OPINION AND ORDER

SWEENEY, Judge

Petitioner seeks compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 to -34 (2006), alleging that her son, M.L., sustained injuries caused by a diphtheria-tetanus-acellular pertussis ("DTaP") vaccine. In a September 28, 2012 decision, the special master denied petitioner's request for compensation. Before the court is petitioner's motion for review of the special master's decision. For the reasons set forth below, the court denies petitioner's motion for review and sustains the decision of the special master.

¹ Vaccine Rule 18(b), contained in Appendix B of the Rules of the United States Court of Federal Claims, affords each party fourteen days in which to object to the disclosure of (1) trade secrets or commercial or financial information that is privileged or confidential or (2) medical information that would constitute "a clearly unwarranted invasion of privacy." Neither party objected to the public disclosure of any information contained in this opinion.

I. BACKGROUND

A. Medical History

M.L. was born in the autumn of 2003 in Leesburg, Florida.² His early medical history is mostly unremarkable. Two days after his discharge from the hospital, he was seen at Silver Lake Pediatrics and diagnosed with jaundice and weight loss. At a subsequent visit to have his weight rechecked he was noted to be doing well. On November 9, 2003, he became so lethargic and pale as to cause his parents to bring him to the emergency department at Leesburg Regional Medical Center (“LRMC”) for evaluation. At the emergency department, M.L. was noted to be alert, active, crying, and with good color. He was assessed with hypothermia at a follow-up visit to Silver Lake Pediatrics.

In addition to the above incidents, M.L. had periodic well-child examinations. During his two-month visit, he received several vaccinations and was noted to have mild postural stridor. Two months later, he received several more vaccinations. Then, during his twelve-month visit, he received one vaccination and was noted to be speaking one to three words and using furniture to walk. At the time of his fifteen-month visit, M.L. was walking, but it was noted that he “[did not] want to talk.” In her affidavit, petitioner indicated that during this early time period, M.L. was developing normally:

At four to five months of age, [M.L.] was developmentally on track. He was rolling over, holding up his head, sitting without assistance, and babbling constantly. At nine months, he was beginning to talk, and at ten months he was starting to walk. At eighteen months, [M.L.] was putting two word phrases together, feeding himself, and walking easily.

M.L. had his eighteen-month well-child examination on April 14, 2005. His temperature was ninety-nine degrees but his examination was otherwise normal. He received varicella, DTaP, haemophilus influenzae type b, and pneumococcal heptavalent conjugate vaccinations during the visit. In her affidavit, petitioner explained what occurred later that day:

Initially, after the administration of his vaccinations, [M.L.] seemed fine. A few hours later, he began to develop goose bumps on his skin, which felt cold to the touch.

² The medical history recounted in this section is derived from two sources: (1) the medical records submitted by petitioner, most of which are discussed in the special master’s decision, and (2) petitioner’s affidavit, Petitioner’s Exhibit 14, which is mentioned, but not quoted, in the special master’s decision. For the sake of clarity, the court expressly notes its references to petitioner’s affidavit in the opinion’s text, and uses footnotes to provide citations to the medical records that contain information not included in the special master’s decision.

After we returned home, I put [M.L.] down for his afternoon nap. He awoke from his nap around 3:00 p.m. screaming uncontrollably, and was extremely hot when I touched him. We immediately checked his temperature with a digital ear thermometer. He had a fever of 100 degrees. We called [Rafael Cheas, M.D., at Silver Lake Pediatrics] who said this was probably because of the vaccines and to use children's liquid Tylenol. [M.L.] was very agitated and feverish all afternoon and into the evening. He wouldn't eat or drink. His fever had risen to 102 by 8pm that night. We again called Dr. Cheas. We told him that the dosages of Tylenol that we were giving [M.L.] were not working to bring the fever down. He said that sometimes this type of reaction can happen with vaccinations and to give it time to pass and not be alarmed. He advised us to use Children's Motrin to reduce [M.L.]'s fever. [M.L.] cried, was limp, drooled, had puffy eyelids, and had a red nose and face. He wheezed and the area around his mouth was white. By midnight, [M.L.]'s temperature was over 103 degrees. We again called Dr. Cheas who advised us to give [M.L.] cool baths and to apply compresses to his stomach and the top of his head to bring his fever down. He also advised us to continue giving [M.L.] Children's Motrin. By 2:00 a.m., [M.L.]'s fever had risen to 104.4 degrees. He still drooled, but now his tongue stuck out and was swollen. His lips were also swollen so large that the area around his mouth was white. He had thrown up his dose of Children's Motrin. He was completely limp. His head rolled from side to side. We spent the rest of the night with [M.L.] in the bathtub without substantial change. By 7am, we called Dr. Cheas and informed him we would be waiting at his office when he opened his doors at 8:00 a.m. [M.L.] was limp, not responding to his name. He was hot and dry to the touch. His face was very pale, his cheeks had bright red splotches on them, and the area around his mouth remained white in color. His lips were swollen and protruded outward. His tongue was swollen beyond his front teeth, and he had difficulty breathing.

As recounted in petitioner's affidavit, M.L.'s parents brought M.L. to Silver Lake Pediatrics during the morning of April 15, 2005.³ M.L. presented with the following complaints: vomiting, fever, and not drinking. M.L.'s parents provided a history of the events that had occurred since M.L.'s visit to the office the previous day: M.L. had a fever of 104.8 degrees at 4:00 p.m. on April 14, 2005, and was given Tylenol; his fever decreased to 102-103 degrees by 8:00 p.m., but later increased; and M.L. experienced facial, lip, and tongue swelling. A physical examination revealed that M.L. was alert, with a strong cry, and "(not toxic) but sick." In addition, M.L. had a flushed face, a "more or less" swollen upper lip, regular heart rhythm and rate, and "no focal neurological signs." The impression was noted as "[h]igh fever, some angioedema of the face, questionable stridor, [and] no wheezing."

³ See Pet'r Ex. 19.

While at Silver Lake Pediatrics, M.L. was given Decadron and epinephrine.⁴ In addition, an ambulance was called to transport him to the emergency department at LRMC. Emergency Medical Services (“EMS”) received the call at 9:18 a.m., and upon their arrival at 9:31 a.m., reported the following:⁵

[Patient] is 18 months old. [Patient] found sitting on father’s lap at Pediatrics Unit. Patient had 18 month immunizations yesterday at 10:30. Patient by 16:00 yesterday was showing skin pigmentation problems, red blotches, . . . febrile skin temps & edema of tongue, mouth & lips. [Patient’s] airway is open. [Patient] is agitated & crying. [Patient] is not lethargic. [Patient’s] clothing was removed for temp control and fluids given . . . [Patient’s] lethargy continued to improve during process of call. [Patient] has vomited x1 today.

[Patient’s] skin red, hot, dry & blotchy. Cyanosis of lips. No pallor or diaphoresis. . . . Equal clear & bilat lung sounds, no abnormal sounds auscultated.

EMS personnel assessed M.L. with an allergic reaction. They placed him on oxygen at 9:43 a.m. and subsequently noted oxygen saturation levels of 97% at 9:47 a.m., 95% at 9:52 a.m., and 97% at 9:57 a.m. The ambulance arrived at LRMC at 10:00 a.m.

Emergency department triage notes reflect that according to the EMS personnel, M.L. experienced the onset of his reaction at 4:00 p.m. the previous day, and that he became flushed, had swelling of his face and tongue, was red, and had a fever.⁶ His vital signs were obtained, revealing a temperature of 102.6 degrees and an oxygen saturation level of 99%. He was then seen by an emergency department physician at 10:40 a.m., who recorded a history of tongue swelling and facial redness, an onset of drooling and lip swelling that morning, an inability to swallow, and an onset of fever the prior afternoon.⁷ The physician’s review of systems revealed shortness of breath, rash, and swelling. During his physical examination, the physician noted no issues aside from M.L. being in pain/distress. He specifically indicated, among other things, that M.L.’s neurological status was at baseline. Upon reassessment, M.L. was not in distress and his temperature had decreased to 100.2 degrees. The physician diagnosed M.L. with acute anaphylaxis, noted that M.L.’s symptoms had resolved, but decided to admit M.L. for further treatment and observation. During his admission, M.L. was given a diagnosis of “vaccine

⁴ The record reveals that the special master mistakenly identified epinephrine as ephedrine. See Pet’r Ex. 19.

⁵ See Pet’r Ex. 5 at 5.

⁶ See Pet’r Ex. 3 at 178.

⁷ See Pet’r Ex. 3 at 176.

adverse reaction [with secondary] fever, angioedema, and anaphylactoid reaction.” He was discharged on April 16, 2005, and his parents were directed to take him to his pediatrician in one week for a follow-up examination.

In her affidavit, petitioner describes M.L.’s condition during and subsequent to his hospitalization as follows:

At the hospital, [M.L.] appeared disoriented. He was flushed, agitated, crying, unresponsive and feverish. [M.L.]’s vitals were checked frequently. Anytime a doctor or nurse would enter his room he would panic. He was extremely tired, barely ate, drank, or talked. . . .

The next day, April 16, 2005, [M.L.]’s fever had subsided. His blood work appeared to be OK, and he was no longer exhibiting any anaphylactic activity. He was discharged from the hospital. [M.L.] was still very tired and weak from his hospital stay.

Petitioner further indicates in her affidavit that she and M.L.’s father put M.L. to bed early and that the next morning, the following events transpired:

Around 8:00 a.m. Sunday morning, April 17, 2005, our son awoke screaming for his dad. Frank rushed to his room only to have [M.L.] push him away when he tried to pick him up. He stared at Frank as if he had no idea who he was. Frank noticed that [M.L.]’s skin was cold to the touch and yelled to me to grab a thermometer to take [M.L.]’s temperature. The first reading was 95.7 degrees. Even after giving him a warm bath and heating up his clothes in the dryer, his temperature still was only 96.5 degrees. I then called Dr. Cheas, who instructed us to give [M.L.] some warm milk or some food to raise his temperature. [M.L.] was not interested in drinking the milk, but he did try to eat an egg I had made for him. I observed [M.L.] as he proceeded to raise the spoon to his mouth. He got it halfway there, but then had an upper torso convulsion and facial grimace that lasted about 15 to 30 seconds. Frank and I looked at each other and Frank said, “what the heck was that?” [M.L.] never got the spoonful of food to his mouth. He slowly lowered the spoon back to his plate. He again proceeded to raise the spoon now in ultra-slow motion up to his mouth all over again. He got halfway to his mouth again and went into another facial grimace. This one was more severe. His head jerked from side to side. His arm with the spoon in it froze in place. His upper torso area spasmed and convulsed for 15 to 30 seconds. I started calling out [M.L.]’s name to get his attention. [M.L.] lowered the spoon down to his plate like nothing had happened. He looked completely dazed and proceeded to try to bring the spoon to his mouth a third time. When he got the spoonful about halfway up to his mouth, he froze. His mouth went into a very severe facial grimace. His bottom lip dropped downward

exposing his lower gums. His jaw was clenched tight. His eyes became unfocused and glazed. His head began jerking violently left and right so severely that he suddenly pitched forward, and we had to catch him to keep him from cracking his forehead on the side of the highchair tray. Frank called 911. While he was on the phone, I continued to call [M.L.]’s name repeatedly. I tried clapping my hands, rubbing my hands up and down [M.L.]’s arms and pinching the top of his hand, but could not get him to respond to me. He was just staring straight ahead. The ambulance crew arrived within a matter of minutes. The fire crew arrived first followed by the rescue crew. The fire crew came in and immediately assessed [M.L.]’s temperature at 95.1 degrees. He was still in his highchair as this was the safest place for him while he was having the convulsions. [M.L.] was dazed, confused, pale, and not speaking. The rescue team had us take [M.L.] out of the highchair and into his bedroom where they took his vitals and assessed him. Once again his temperature registered low but was now at 96.6 degrees. We gave the rescue team the synopsis of what had transpired over the past twenty-four hours, as well as what had happened since [M.L.]’s vaccinations the previous Thursday. The decision was made to transport [M.L.] once again to Leesburg Regional Medical Center for evaluation.

EMS was contacted at 9:30 a.m., and the responders found M.L. to be warm, flush, and agitated. They recorded M.L.’s temperature as 95.7 degrees, and measured his oxygen saturation level as 99%.⁸ Due to his low temperature, EMS transported M.L. to the hospital.

M.L. was seen in the emergency department at LRMC at 10:14 a.m.⁹ Emergency department nurse’s notes from the same time indicate the history provided by one of M.L.’s parents:¹⁰

Parent state[s] _____ child awoke calling Dad. Child seemed like he didn’t recognize Dad. Child was awake. While trying to feed child breakfast. Had 3 episodes of becoming stiff, grinding teeth [with] non _____ eye staring. Episodes lasted x 10 seconds each. Parent took _____ temp. 96? Parent

⁸ See Pet’r Ex. 5 at 10.

⁹ See Pet’r Ex. 3 at 54.

¹⁰ The special master quoted a portion of these notes, averring that they reflected events that occurred while M.L. was at the hospital. However, because the notes are prefaced with “[p]arent state[s],” and because the time of the notes is the same time that M.L. was signed in at the emergency department, it is apparent that the events described in the notes predate M.L.’s arrival at the emergency department. See Pet’r Ex. 3 at 54-55.

swaddled child & called Dr. Cheas. Was told to feed child and wait 1 hour to see if temp [increased]. Child ate well but temp wouldn't come up per parent. . . .

Also mild swelling _____ upper lip this a.m. Lungs clear.

M.L. had a temperature of 99.7 degrees, an oxygen saturation level of 100%, and was active, alert, and smiling. In contrast, petitioner indicated in her affidavit that upon arrival at the hospital, M.L. "was disoriented, limp, and his skin was cold to the touch. He did not respond to us and when he did look at us, he wasn't quite sure who we were." M.L. was admitted to the hospital due to suspected seizures.

Petitioner described some of M.L.'s behavior after he was admitted:

We tried to get [M.L.] to eat. However, he got upset and became frantic. His head jerked from side to side, and his face grimaced and clenched. I picked him up and held him. He grabbed me tightly and vomited down my back. After a short period of time, we again attempted to have [M.L.] eat and drink. [M.L.] once again started making very severe facial grimaces, clenched his jaw and tensed his upper torso. [M.L.] started making gagging sounds and did not respond to either Frank or me. Frank turned [M.L.] on his side and leaned him in a forward position. He . . . once again began vomiting.

Due to [M.L.]'s disorientation, convulsions, vomiting, altered sensations and lack of coordination, Dr. Cheas ordered a pediatric neurological consultation. . . . The next day, [M.L.] had more convulsive activity. He was disorientated and still did not talk.

During his hospitalization, M.L. underwent a variety of tests. An electroencephalogram ("EEG") was performed on April 18, 2005, which was interpreted by Eugene Tan, M.D., a neurologist, as follows: "This is an essentially normal sleep EEG study, but I would suggest a strong clinical correlation because of the presence of induced rhythmic wave on the left posterior hemisphere which could be suspicious of some focal activity."¹¹ Dr. Tan recommended a repeat EEG, in part due to the existence of an artifact on the first EEG. The second EEG was performed on April 20, 2005, about which Dr. Tan noted: "This is an abnormal electroencephalogram because of the presence of the intermittent sharp-like wave and rhythmic slow wave in the left posterior hemisphere region, . . . suspicious of focal activity in that area."¹²

¹¹ See Pet'r Ex. 3 at 73-74.

¹² See Pet'r Ex. 3 at 72.

Dr. Tan evaluated M.L. on April 20, 2005.¹³ M.L.'s parents supplied a history of events, which was recounted by Dr. Tan as follows:

This is an 18-month-old white male, who was in his usual state of good health until last Thursday when he had four vaccinations received at Dr. Cheas' office The patient was giving them a good fight, stiffening up and even bent the needles with shots in his right thigh, and then he developed a fever several hours later and through to that night. At one point, his temperature went up to as high as 103 Fahrenheit and his tongue swelled up. Face and lips puffed up also. The next morning, they went and saw Dr. Cheas in his office and he gave him Decadron and Benadryl and called the ambulance to bring him in to our ER. He was admitted for 24-hour observation and seems to be covered [sic] well.

During that admission, the father claimed that while he was inside his crib, he was acting a bit groggy and slumped forward and hit his right face on the railing of the crib, but no loss of consciousness and he was discharged in good condition. The following morning, he was noted to be hypothermic when the father tried to pick him up/wake him up and he was kind of unresponsive and lethargic at that time, hence, they checked his temperature and said to be 96 Fahrenheit. Because of this, they had to call Dr. Cheas again and he advised them to give him a warm bath, give him some juice and then when they were trying to feed him breakfast that Monday, he had three episodes while sitting in a chair, his face would tense up, lower lips were pulled down and aside. He would turn his head to the right and to the left with eyes staring straight and unresponsive and then would act a little lethargic after each episode. Those episodes lasted about 10 seconds each and then he would eat his breakfast a bit in between. The father claimed that he was clenching and grinding his teeth also during those episodes and after the third one, he slumped over and almost hit his bowl of food in front of him and was even more lethargic. Because of this, they decided to bring him to our ER.

During Dr. Tan's physical examination of M.L., he found no neurological problems. His diagnosis was: "Possible seizures but I cannot rule out the possibility that this seizure could be related to a reaction to the vaccines at this time versus primary epilepsy." This diagnosis was consistent with an April 19, 2005 progress note, which listed an impression of questionable clinical seizures, viral syndrome, and vaccine adverse reaction.

Also during this hospitalization, M.L.'s parents reported two more "seizure like" episodes, after which M.L. behaved normally. Dr. Cheas submitted a report to the Vaccine Adverse Event Reporting System ("VAERS") on April 20, 2005, noting that M.L. received his April 14, 2005 vaccinations at 10:45 a.m. and listing as adverse events angioedema and possible

¹³ See Pet'r Ex. 3 at 158-60.

seizures. A progress note from April 21, 2005 reflected that M.L. had not experienced any “seizure-like activity” since April 18, 2005, and was “acting more like his normal self.” The note also included a question as to whether M.L.’s seizures were idiopathic or related to his vaccinations. M.L. was discharged from the hospital later that day with a prescription for Tegretol, an anticonvulsant, and instructions to schedule a magnetic resonance imaging (“MRI”) study within the following one to two weeks and a follow-up visit with Dr. Tan within the following three weeks.

In her affidavit, petitioner recounted M.L.’s condition upon returning home from the hospital:

By the time we got to the house, [M.L.] was very agitated. He did not recognize familiar surroundings or people. When we took him into our bedroom, he became hysterical, screamed and thrashed about. . . . This episode lasted just over half an hour. These types of episodes, as well as convulsions and [M.L.]’s complete lack of speech continued over the next two weeks.

As directed, M.L. had an MRI study performed on April 26, 2005; it was normal. During a May 5, 2005 pediatric visit, Dr. Cheas noted that M.L. so far had not had a seizure. However, M.L.’s parents noticed “abnormal” behavior, including head-holding and screaming, restlessness through the night, a lack of interest in books, tip-toe walking, and constipation. Dr. Cheas indicated that his impression was a history of seizures and questioned whether M.L.’s signs, symptoms, or condition were vaccine-related. Then, during a May 12, 2005 follow-up visit with Dr. Tan, M.L.’s parents reported that M.L. continued to experience episodes, manifested by hand clenching, teeth grinding, and the tensing of his facial muscles. They also reported that M.L. was more clumsy, tended to tip-toe walk, and lost interest in reading books.¹⁴ Dr. Tan assessed a seizure disorder, “GEN-tonic type.”

Dr. Tan continued to treat M.L. throughout the summer 2005. During this time period, he adjusted M.L.’s Tegretol dosage on several occasions. He also noted petitioner’s report that M.L. was experiencing almost daily episodes of teeth grinding, sometimes accompanied by staring and/or facial grimacing, all followed by lethargy, and that M.L. sometimes would walk like he was drunk.¹⁵ And, during a July 12, 2005 visit, M.L.’s parents reported that M.L. had begun to talk more, but was not at the level he was at prior to his vaccinations. Dr. Tan referred M.L. to a speech therapist, who evaluated M.L. on July 21, 2005. M.L.’s parents told the therapist that M.L. lost most of his vocabulary and was only saying three words. They further indicated that M.L. had been advanced with spatial relations. The therapist could not conduct formal testing during the visit because M.L. did not follow oral or motor commands. She

¹⁴ See Pet’r Ex. 6 at 1.

¹⁵ See Pet’r Ex. 6 at 3.

recommended speech therapy once per week to increase M.L.'s vocabulary. In her affidavit, petitioner stated:

[M.L.'s] speech improvement deteriorated when his medication levels were adjusted.

We were disturbed by what was happening to [M.L.] [M.L.] now had upper body convulsions and facial grimaces. In addition, he had stopped talking completely on April 14, 2005. His last fluent words were on the day of his visit with Dr. Cheas for his 18 month vaccinations. We were also upset with [M.L.]'s inability to feed himself. He looked at the food as if it weren't there or as if he couldn't pick it up to get it to his mouth. He no longer was able to use a sippy cup and reverted to using a 4 ounce bottle. He often choked on food. His throat was so sore and tender for the first couple of months after the vaccines that he only ate baby food or very soft food that was easy to swallow. This is a little boy who loved all of his vegetables and meats, ate any type of food put in front of him, and who ate with a fork and spoon. He no longer wanted his morning or afternoon snacks. He lost weight. He was in the upper 80 to 90 percentile for his height so this made him thin. [M.L.] would grind his teeth on his bottle nipples and sippy cups. His tongue hung out and he drooled constantly. He bumped into things due to poor coordination.

On September 26, 2005, M.L. was evaluated by a pediatric neurologist, Renato Gonik, M.D. He recounted M.L.'s history:¹⁶

[M.L.] was doing well until he was 18 months of age, at which time he received four immunizations at one time. . . . Within a few hours he developed an anaphylactoid reaction, which consisted of high fever up to 104.9 degrees Centigrade [sic] and facial and tongue swelling. He was later noted to be limp and on that day the temperature was noted to be low in the mid 90s and he had a spell while eating of head shaking side-to-side and drooping of his head. At that time he was admitted to the hospital where he was believed to have a seizure. . . . Since then [M.L.] continued to have spells that are described as shivering accompanied by bruxism, lasting approximately 45 seconds or so. This is not accompanied by a postictal phase. There are no clear descriptions of generalized or focal tonic-clonic activity. . . . Since the day of the shots, [M.L.] has lost the ability to speak as he had previously. Up to that time he had a normal vocabulary for his age and was attempting to put words together such as "I want". Since then, however, he is mostly able to utter only unintelligible sounds, and occasionally will utter a recognizable word. There has not been noted any motor regression.

¹⁶ See Pet'r Ex. 18 at 1.

Based on his history of seizures and language regression, Dr. Gonik suggested that M.L. might suffer from Landau-Kleffner syndrome. He recommended another EEG.

During a follow-up visit with Dr. Tan on November 10, 2005, M.L.'s parents reported that M.L.'s hair was falling out and that he was suffering from almost-daily spells. Dr. Tan assessed complex partial seizures, reduced M.L.'s Tegretol dosage, and started M.L. on Keppra, another anticonvulsant. In her affidavit, petitioner explained what happened next:

[M.L.] did well on the medications for about two days, but on the third day, he began acting differently. His coordination was worse, his sleep pattern changed, he had "restless legs," and he started pulling at his skin. By Thanksgiving week, [M.L.] seemed to be spiraling out of control. His eyes were extremely sensitive to sunlight and he tried to put things into them. He pulled his hair and toes apart. [M.L.] screamed, seemed to hallucinate, and often did not recognize Frank or me. We called the doctor and [M.L.]'s medication levels were altered, helping to stop some of his symptoms.

On Thanksgiving morning, [M.L.] spiked a temperature of 103.9. The next day, unable to keep his temperature down, we brought him to Arnold Palmer Children's Hospital.

M.L. was admitted to the hospital for evaluation on November 25, 2005, after experiencing screaming episodes, seizure-like responses to colors and shapes on the wall that he might have hallucinated, light sensitivity, and a high temperature. His simple partial seizures had changed to complex partial seizures, and were occurring more frequently. During this hospitalization, M.L. underwent additional testing. A computed tomography scan and MRI study were within normal limits. The results of a November 26, 2005 EEG were as follows:¹⁷ "This is [an] abnormal EEG . . . for age secondary to biposterior quadrant slowing which was near continuous, possibly indicating postictal state, however, structural lesion could not be entirely ruled out. No epileptiform discharges were seen. No clinical or subclinical seizures were recorded. Clinical correlation is recommended." M.L. underwent a twenty-four-hour video EEG the following day, with the following results:¹⁸

This is a mildly abnormal video EEG monitoring for age, secondary to presence of mild intermittent bi-posterior quadrant slowing. No epileptiform discharges were seen.

Patient's typical spells captured during this EEG associated with fisting of the right hand, clenching of the teeth, shivering-like of the mouth and clenching of

¹⁷ See Pet'r Ex. 7 at 83.

¹⁸ See Pet'r Ex. 7 at 81.

the teeth along with right-hand fisting did not have electrographic seizure correlate. Clinical correlation is advised.

M.L. was weaned from Tegretol and Keppra during this hospitalization. He was discharged on November 29, 2005, with a primary diagnosis of stereotypic behavior without infection or seizure activity, and a secondary diagnosis of speech delay and possible pervasive developmental disorder.¹⁹

On December 27, 2005, M.L. had his hearing evaluated by Clifford Dubbin, M.D. Dr. Dubbin noted that M.L. had fluid behind both ears causing conductive hearing loss. He also remarked that in his past experience, he had seen nerve damage caused by a vaccination.

M.L. was evaluated by another pediatric neurologist, Jasna Kojic, M.D., on January 9, 2006. Dr. Kojic noted that M.L. had stopped speaking and his fine motor skills regressed after his April 2005 hospitalization. She also noted that M.L.'s screaming and screeching episodes stopped after he was weaned from the anticonvulsants. Dr. Kojic's impression was:

It appears at this point that his developmental delay, repetitive and ritualistic behavior would probably categorize him in autistic spectrum disorder category, most likely pervasive developmental disorder-not otherwise specified. It is puzzling that apparently his development was age appropriate up until 18 months when he had his routine immunization resulting in severe allergic reaction.

She recommended the continuation of speech therapy and the initiation of occupational therapy.

On January 24, 2006, M.L. was evaluated by a child development specialist, Joseph J. Keeley, Jr., M.D.²⁰ During the neurological portion of his physical examination, Dr. Keeley noted that M.L. had mild generalized hypotonia and tended to walk on his toes as a result of his axial hypotonia. Dr. Keeley reported his impression:

1. Expressive aphasia. This is a young man who clearly at this time has had steady improvement since he last saw Dr. Kojic and no longer makes the diagnosis of pervasive developmental disorder. But instead, has almost pure aphasia.
2. History of delayed anaphylactic reaction secondary to immunizations. By parent's history, which would need to be correlate [sic] from the history of the hospital, when he represented to the hospital he seemed to be in clinical shock with poor circulation, hypothermia and lethargic.

¹⁹ See Pet'r Ex. 7 at 5.

²⁰ See Pet'r Ex. 12 at 7-8.

3. History of focal seizures with normal studies. [M.L.] continues to have some rather steady difficulties with expressive language. But otherwise, is functioning very well.

M.L. had another EEG on March 30, 2006, which was within normal limits. Dr. Keeley then reevaluated M.L. on April 24, 2006.²¹ During his neurological examination, Dr. Keeley found that M.L. was “markedly hypotonic and walk[ed] with an exaggerated lordosis and up on the tips of his toes,” that there were “no asymmetries to his gait,” and that when M.L. stood, he tended to “go into bilateral back knee, which with his other hypotonia does make him somewhat more unstable.” His impression included:

1. [M.L.] is a young man who continues to recover from whatever insult it was that he had. He has become steadily more actively engaged with both examiner and his parents and his speech has moved up six months on the Caputi scale and there [sic] months since his last visit here. His speech is becoming to be right at the borderline range after having been clearly delayed.
2. Hypotonia. His motor skills and tripping seem to be not due to any focal weakness but to the fact that he has generalized hypotonia that has not changed from the last examination. There is no sign of central nervous system problems at this time.²²

Overall, Dr. Keeley remarked that M.L. had “shown steady improvement in all areas.” Indeed, M.L. continued to progress with the assistance of speech, occupational, and physical therapy.

B. Procedural History

Petitioner filed a petition for compensation under the Vaccine Act on June 1, 2006. After filing the necessary medical records and her affidavit, petitioner filed an amended petition on September 12, 2006, seeking a ruling in her favor. Respondent filed the report required by Vaccine Rule 4(c) on October 10, 2006, averring that compensation should be denied. Several months later, the parties filed reports prepared by their respective expert pediatric neurologists: Marcel Kinsbourne, M.D. for petitioner and John T. MacDonald, M.D. for respondent. The special master convened a hearing on September 14, 2007, during which he heard testimony from the two experts. Upon reviewing the posthearing briefs, the special master advised the parties that he had identified a major flaw in petitioner’s case; namely, that Dr. Kinsbourne had relied on

²¹ See Pet’r Ex. 12 at 1-2.

²² The special master included the comment concerning the lack of central nervous system problems in his decision, but implied that it was made in relation to the January 2006 visit.

statements by petitioner that were not in the record and that the special master believed conflicted with the medical records. Another serious flaw raised by the special master was Dr. Kinsbourne's lack of qualifications in interpreting EEGs. Ultimately, the special master shared with the parties his draft decision outlining the deficiencies in petitioner's case.

In response to the special master's draft decision, petitioner filed a variety of documents. Most notably, she filed an unsigned narrative containing background information and a description of the events that occurred on and after April 14, 2005. She had prepared the narrative at the direction of counsel to assist counsel's prosecution of the case and her expert's preparation of his report.²³ Petitioner's counsel received the narrative on March 27, 2006, and there does not appear to be any dispute that this is the document relied upon by Dr. Kinsbourne in preparing his report. Moreover, comparing this narrative to petitioner's affidavit, which was executed on August 25, 2006, and filed on September 8, 2006, prior to the hearing, it is clear that the affidavit was derived from the narrative and contains information from the narrative that pertains to causation. It also bears noting that the special master repeatedly sought the oral testimony of petitioner, but that petitioner declined to testify.

In addition, after obtaining, over respondent's objections, the special master's approval for additional time to consult with another pediatric neurologist and the opportunity to obtain a report addressing M.L.'s April 25, 2005 EEG from an individual with expertise in reading EEGs, petitioner filed a supplemental report from Dr. Kinsbourne. Then, again over respondent's objections, the special master permitted petitioner to obtain a neurological evaluation from another pediatric neurologist, Ronald Davis, M.D. As recounted in an October 6, 2010 letter, Dr. Davis evaluated M.L. on June 16, 2010, and concluded, based on the history provided by M.L.'s parents and a physical examination,²⁴ that M.L.'s neurological issues were caused by the anaphylactic reaction following his April 14, 2005 vaccinations. Petitioner filed the letter prepared by Dr. Davis on October 13, 2010.

After respondent filed a supplemental report from Dr. MacDonald, the parties filed closing briefs. In a September 28, 2012 decision, the special master stated that he had re-reviewed the entire record and found that petitioner had not cured either the problems associated with Dr. Kinsbourne formulating his opinion based on significant medical information provided by petitioner that was not reflected in the medical records or the problems related to the fact that M.L.'s initial anaphylactic reaction had resolved. The special master ultimately concluded that petitioner did not establish, by a preponderance of the evidence, a medical theory causally connecting an anaphylactic reaction to a focal brain injury, or a logical sequence of cause and effect actually linking M.L.'s initial anaphylactic reaction to his neurological injuries. Thus,

²³ At the hearing before the special master, petitioner's counsel stated that it was the law firm's standard practice to obtain such narratives from its clients.

²⁴ It is unclear from the text of the letter whether Dr. Davis had access to any of M.L.'s medical records.

although petitioner established that the DTaP vaccine caused M.L.'s initial anaphylactic reaction, she was unable to satisfy the Vaccine Act's requirement that a vaccine-related injury last at least six months to be compensable. The special master therefore denied petitioner's request for compensation. Petitioner now seeks review of the special master's decision. Respondent opposes petitioner's motion for review, and the court heard argument on the parties' competing positions on March 5, 2013.

II. DISCUSSION

The United States Court of Federal Claims has jurisdiction to review the record of the proceedings before a special master, and upon such review, may:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
- (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). In the instant case, petitioner enumerates, pursuant to Vaccine Rule 24, three objections to the special master's decision. First, petitioner asserts that the special master improperly concluded that she did not satisfy the test for proving causation-in-fact set forth in Althen v. Secretary of HHS, 418 F.3d 1274 (Fed. Cir. 2005). Second, petitioner contends that the special master improperly used a credibility determination of her expert to shield his decision on causation. Third, petitioner avers that the special master erred by failing to evaluate the evidence related to M.L.'s neurological injuries. The court addresses each objection in turn.

A. Causation-In-Fact

1. Proving Causation Under the Vaccine Act

Pursuant to 42 U.S.C. § 300aa-13(a)(1), the court shall award compensation if a petitioner proves, by a preponderance of evidence, all of the elements set forth in 42 U.S.C. § 300aa-11(c)(1),²⁵ and if there is not a preponderance of evidence that the illness is due to factors

²⁵ Subsection (c)(1) requires, among other things, that the following elements be satisfied: (1) that the vaccine in question is set forth in the Vaccine Injury Table ("Table"); (2) that the vaccine was received in the United States or in its trust territories; (3) that the injured person either sustained an injury as a result of the administration of a Table-designated vaccine

unrelated to the administration of the vaccine. A petitioner can recover in one of two ways: either by proving an injury listed on the Table or by proving causation-in-fact. See 42 U.S.C. §§ 300aa-11(c)(1)(C), -13(a)(1). Under the first method of recovery, a petitioner must demonstrate that the injury was sustained within the time frame set forth in the Table. Id. § 300aa-11(c)(1)(C)(I), -14(a). “If petitioner can make such a showing, causation is presumed and petitioner is deemed to have made out a prima facie case of entitlement to compensation under the Act.” Whitcotton v. Sec’y of HHS, 81 F.3d 1099, 1102 (Fed. Cir. 1996).

To establish a prima facie case when proceeding on a causation-in-fact theory, a petitioner must “prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface v. Sec’y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999). “[T]o show that the vaccine was a substantial factor in bringing about the injury, the petitioner must show ‘a medical theory causally connecting the vaccination and the injury.’” Id. at 1352-53 (quoting Grant v. Sec’y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (per curiam)). In other words, “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury,’” id. at 1353 (quoting Grant, 956 F.2d at 1148), and “[t]his ‘logical sequence of cause and effect’ must be supported by a sound and reliable medical or scientific explanation,” Knudsen v. Sec’y of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994) (citing Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993); Jay v. Sec’y of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993)); see also 42 U.S.C. § 300aa-13(a)(1) (“The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.”). However, medical or scientific certainty is not required. Knudsen, 35 F.3d at 548-49; Bunting v. Sec’y of HHS, 931 F.2d 867, 873 (Fed. Cir. 1991).

In Althen, the United States Court of Appeals for the Federal Circuit (“Federal Circuit”) articulated a three-part test, based on this prior precedent, explaining what a petitioner must show to prove causation-in-fact under the Vaccine Act:

[Petitioner]’s burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

418 F.3d at 1278. Causation-in-fact can be established with circumstantial evidence, i.e., medical records or medical opinion. Id. at 1279-80 (citing 42 U.S.C. § 300aa-13(a)(1)). And, all

for a period of more than six months after the administration of the vaccine, suffered illness, disability, injury, or condition from the vaccine that resulted in inpatient hospitalization and surgical intervention, or died from the administration of the vaccine; and (4) that the petitioner has not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury or death. 42 U.S.C. § 300aa-11(c)(1).

three prongs “must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” Pafford v. Sec’y of HHS, 451 F.3d 1352, 1355 (Fed. Cir. 2006).

Once a petitioner has established a prima facie case, the burden shifts to the respondent to show, by a preponderance of the evidence, that the injury was caused by a factor unrelated to the vaccine. 42 U.S.C. § 300aa-13(a)(1)(B); Shalala v. Whitecotton, 514 U.S. 268, 270-71 (1995); de Bazan v. Sec’y of HHS, 539 F.3d 1347, 1352 (Fed. Cir. 2008). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec’y of HHS, 991 F.2d 1570, 1575 (Fed. Cir. 1993). Regardless of whether the burden ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a prima facie case. See Stone v. Sec’y of HHS, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[E]vidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.”); de Bazan, 539 F.3d at 1353 (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner’s evidence on a requisite element of the petitioner’s case-in-chief.”).

Petitioner contends that she has satisfied all three prongs of the Althen test. The court addresses each prong in turn.

2. Althen Prong One

Under the first prong of the test in Althen, a petitioner must demonstrate that the vaccine at issue can cause the injury alleged. Pafford, 451 F.3d at 1355-56. To satisfy this prong, “a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner’s case, although the explanation need only be ‘legally probable, not medically or scientifically certain.’” Broekelschen v. Sec’y of HHS, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (quoting Knudsen, 35 F.3d at 548-49); see also Moberly v. Sec’y of HHS, 592 F.3d 1315, 1324 (Fed. Cir. 2010) (“[T]he special master is entitled to require some indicia of reliability to support the assertion of the expert witness.”). However, “conclusive evidence in the medical literature linking” the vaccine to the injury alleged is not required. Andreu v. Sec’y of HHS, 569 F.3d 1367, 1378 (Fed. Cir. 2009); see also id. at 1379 (“‘[I]n a field bereft of complete and direct proof of how vaccines affect the human body,’ a paucity of medical literature supporting a particular theory of causation cannot serve as a bar to recovery.” (quoting Althen, 418 F.3d at 1280)). Nor is a petitioner required to “provide proof of the specific biological mechanism leading to the injury at issue.” Stone, 676 F.3d at 1384.

Petitioner asserts that she established, through the expert opinion of Dr. Kinsbourne, a medical theory causally connecting the DTaP vaccine and the injuries suffered by M.L. In his report,²⁶ Dr. Kinsbourne stated:

²⁶ Dr. Kinsbourne’s report is designated Petitioner’s Exhibit 20.

[M.L.'s] anaphylaxis consisted of two components: An immediate response which was reversible, but which morphed into a late-phase reaction that lasted several days. The same trigger that produces the immediate symptoms also produces the late stage reaction, without any new exposure to the causative antigen. The immediate anaphylactic reaction is mediated by IgE. The late-phase anaphylactic reaction is mediated by Th2 cells that release cytokines. Benadryl and epinephrine are used to control the immediate reaction and Decadron is used to control the late-phase reaction. A late-phase reaction occurs in about 10 percent of anaphylactic reactions.

. . . .

In summary, the anaphylactic reaction sometimes progresses into a phase in which widespread inflammation as well as anoxia causes organ damage. In [M.L.]'s case, the damaged organ was the brain.

In support of this theory, Dr. Kinsbourne offered a quotation from a medical text explaining the two-phase reaction:

Many local type I hypersensitivity reactions have two well-defined phases The immediate, or initial, response is characterized by vasodilation, vascular leakage, and depending on the location, smooth muscle spasm or glandular secretions. These changes usually become evident within 5 to 30 minutes after exposure to an allergen and tend to subside in 60 minutes. In many instances (e.g., allergic rhinitis and bronchial asthma), a second, late-phase reaction sets in 2 to 24 hours later without additional exposure to antigen and may last for several days. This late-phase reaction is characterized by infiltration of tissues with eosinophils, neutrophils, basophils, monocytes, and CD4+ T cells as well as tissue destruction, typically in the form of mucosal epithelial cell damage.

Given that M.L. did not exhibit symptoms during the five to thirty minutes immediately following his vaccinations, Dr. Kinsbourne was asked to clarify the applicability of his theory during the hearing. He testified that M.L.'s initial reaction was a delayed onset anaphylactic reaction. That reaction, he said, resolved clinically, but he postulated that the reaction persisted

in a smoldering form, damaging part of M.L.'s brain. According to Dr. Kinsbourne, this brain damage caused M.L.'s seizures,²⁷ speech problems, and right-sided clumsiness.²⁸

When asked to provide support for his theory that an anaphylactic reaction could cause a focal brain injury, Dr. Kinsbourne testified that he did not know whether a link between anaphylactic reactions and focal brain injury was generally accepted, or even discussed. He had never seen an anaphylactic reaction lead to a focal brain injury, did not find any support for a link in the medical literature, and possessed an incomplete understanding of how the reaction could evolve into a focal brain injury. However, Dr. Kinsbourne proposed three mechanisms that could explain how a focal brain injury could follow from an anaphylactic reaction: continuing widespread inflammation, cytokine release, and edema-induced loss of oxygen. He could not identify which, if any, of the mechanisms was involved in this case. Indeed, he testified that "we don't know what was happening on the tissue level," but that "something could have been going on."

In evaluating the medical theory offered by Dr. Kinsbourne, the special master reviewed Dr. Kinsbourne's initial report,²⁹ the accompanying medical literature, and Dr. Kinsbourne's

²⁷ The special master noted that Dr. MacDonald questioned whether M.L.'s episodes of facial grimacing, jaw clenching, upper body tensing, and staring were actually seizures. Nevertheless, for simplicity's sake, the court refers to the episodes as seizures throughout its opinion.

²⁸ In her memorandum in support of her motion for review ("Mot."), petitioner suggests that an article submitted by respondent regarding hypotonic-hyporesponsive episodes following vaccination supports Dr. Kinsbourne's theory. However, Dr. Kinsbourne did not claim that M.L.'s injuries were the result of a hypotonic-hyporesponsive episode ("the sudden onset of limpness, decreased responsiveness, and pallor or cyanosis occurring within 48 hours after immunization, age 10 years or younger, and duration of event from 1 minute to 48 hours," Resp't Ex. F); rather, he claimed that M.L.'s injuries resulted from a two-phase anaphylactic reaction (characterized by "[v]ascular dilation, edema, smooth muscle contraction, mucus production, [and] inflammation," with the first phase "evident within 5 to 30 minutes" and the late phase setting in "2 to 24 hours later," Pet'r Ex. 20 tab A). It appears that petitioner is attempting to offer a theory on review despite not having advanced it before the special master. Clearly, the special master could not have been expected to discuss in his decision evidence pertaining to a theory not advanced by petitioner. Nor will the court consider a theory offered for the first time on review.

²⁹ Dr. Kinsbourne's supplemental report does not address whether an anaphylactic reaction can cause a focal brain injury. Rather, it concerns whether the anaphylactic reaction did cause a focal brain injury in M.L. Thus, there was no need for the special master to discuss the supplemental report under the first prong of the Althen analysis.

testimony. He remarked:³⁰

While the literature clearly states that a late-phase reaction can last for several days, Dr. Kinsbourne was unable to point to anywhere in the literature that describes the sequence that presented in this case. Dr. Kinsbourne testified that the literature submitted does not support the notion of anaphylactic shock causing the type of injury in this case. Moreover, Dr. Kinsbourne was unable to find any case reports in support of this type of sequelae. He stated “[h]ad I had a reference available which said something of the order of one in 1000 anaphylactic reactions results not in death but in some permanent focal injury to the brain, I would have filed it with the Court.” Dr. Kinsbourne acknowledged that he has never seen this sequence before and it is beyond rare. Dr. Kinsbourne explained that the mechanism of the April 17 event, almost three days post-vaccination[,] was not totally clear to him and his understanding of how the reaction could evolve in this way is incomplete.

La Londe v. Sec’y of HHS, No. 06-435V, 2012 WL 5351164, at *11 (Fed. Cl. Spec. Mstr. Sept. 28, 2012) (citations omitted). Accordingly, the special master concluded that Dr. Kinsbourne’s medical theory was unreliable. See id. at *18 (“Dr. Kinsbourne’s medical theory is nothing more than a theory—it is untested, he does not know if it is medically accepted, there is no supportive literature that he is aware of and he has never seen such a medical sequence in his experience. In short, it is unreliable.” (citation omitted)), accord id. (“Unfortunately for petitioner this theory fails to pass any reasonable test of reliability.”); see also id. at *12 (“assuming reliable support for Dr. Kinsbourne’s theory”), *19 (“assuming that Dr. Kinsbourne’s medical theory of two phase anaphylactic reaction is reliable”). He therefore held that petitioner “failed to establish a ‘medical theory [causally] connecting the vaccine and the injury[.]’” Id. at *18 (quoting Althen, 418 F.3d at 1278).

Petitioner argues that she met her burden because Dr. Kinsbourne posited a two-phase anaphylactic reaction that included a delayed second stage, medical literature supports the existence of late-phase anaphylactic reactions, Dr. MacDonald agreed that a late-phase anaphylactic reaction is biologically plausible, Dr. Kinsbourne offered three possible mechanisms of injury, and the three proposed mechanisms have been shown in the medical literature to result from an anaphylactic reaction. In other words, petitioner contends that she has established that the processes involved in causing a late-stage anaphylactic reaction— inflammation, cytokine release, and edema-induced loss of oxygen—could also cause a brain injury. However, as reflected in the special master’s decision, there is a gap in the medical theory offered by petitioner.

³⁰ The special master did not separately set out in his decision a discussion of the first prong of the Althen test. Instead, almost all of his discussion of the first prong was contained in his discussion of the second prong.

A plausible medical theory in this case would need to link the following events: a DTaP vaccination, an initial anaphylactic reaction, and a second/late-phase anaphylactic reaction (i.e., a focal brain injury that manifests as seizures, speech difficulties, and/or right-sided clumsiness). The parties agree that a DTaP vaccine can cause an anaphylactic reaction and that, through inflammation, cytokine release, or edema-induced loss of oxygen, a late-phase anaphylactic reaction can be triggered. But, they disagree about whether a focal brain injury can constitute a late-phase anaphylactic reaction. In other words, can the inflammation, cytokine release, or edema-induced loss of oxygen associated with an anaphylactic reaction trigger a focal brain injury? Dr. Kinsbourne opined in his report that it could, but subsequently testified, as noted above, that he had never seen an anaphylactic reaction lead to a focal brain injury, did not find any support for a link in the medical literature, and had an incomplete understanding of how the reaction could evolve into a focal brain injury. In other words, he could not back up his hypothesis with a reliable medical or scientific explanation. The special master did not require petitioner to provide conclusive evidence from the medical literature or proof of the proposed biological mechanisms. Instead, he quite properly required petitioner to carry her burden to bring forward a reliable medical or scientific explanation. Broekelschen, 618 F.3d at 1345; Moberly, 592 F.3d at 1324. Accordingly, the special master's conclusion that petitioner failed to satisfy the first prong of the Althen test by a preponderance of the evidence was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

Because the failure to satisfy one prong of the Althen test forecloses petitioner from establishing causation-in-fact, the court must deny petitioner's motion for review. Nevertheless, the court addresses petitioner's remaining arguments.

3. Althen Prong Two

The special master concluded that even if petitioner had advanced a reliable medical theory causally connecting the DTaP vaccine to M.L.'s injuries, she did not satisfy the second prong of the Althen test: a logical sequence of cause and effect showing that the DTaP vaccine did in fact cause M.L.'s injuries. The Althen test's second prong requires a petitioner to show "that the vaccine was the 'but for' cause of the harm," Pafford, 451 F.3d at 1356, or, in other words, "that the vaccine actually caused the alleged symptoms in [the] particular case," id. (quoting the decision of the special master as recited by the trial court); see also Capizzano v. Sec'y of HHS, 440 F.3d 1317, 1326 (Fed. Cir. 2006) ("A logical sequence of cause and effect' means what it sounds like—the claimant's theory of cause and effect must be logical."). A petitioner need not demonstrate actual causation to a scientific certainty. Moberly, 592 F.3d at 1324; see also Capizzano, 440 F.3d at 1325 ("[R]equiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen . . ."). Moreover, the "medical records and medical opinion testimony" of treating physicians can be "probative" because "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the

vaccination was the reason for the injury.”’ Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1278); accord Andreu, 569 F.3d at 1376.

Petitioner contends that she satisfied the second prong of the Althen test because she provided evidence that the DTaP vaccine can cause an anaphylactic reaction, that such a reaction can cause neurological injuries, that M.L. suffered from neurological injuries, that the timing of M.L.’s injuries was medically appropriate, and that no other likely cause of M.L.’s neurological injuries has been identified. She argues that the special master ignored the evidence in the record supporting her assertion that M.L.’s anaphylactic reaction did cause a focal brain injury and resulting neurological complications. In fact, petitioner alleges, the record is replete with evidence that M.L. was experiencing inflammation and edema-induced loss of oxygen in conjunction with his anaphylactic reaction, which, per Dr. Kinsbourne, could cause a focal brain injury.

Petitioner first finds support for inflammation and edema-induced loss of oxygen in the medical records. She contends that M.L.’s persistent high fever was a symptom of inflammation and that M.L.’s cyanosis of the lips, swelling of the lips, mouth, tongue, and throat, stridor, and shortness of breath were symptoms of edema-induced loss of oxygen. In fact, according to petitioner, “the medical records alone show direct clinical evidence of hypoxia and inflammation of prolonged duration.” Mot. 35.

There are at least two difficulties with petitioner’s reliance on the medical records.³¹ First, Dr. Kinsbourne had access to these very same medical records and, as the special master noted, did not see any test or examination results from M.L.’s hospitalization that would support the existence of widespread inflammation or loss of oxygen. Nor did Dr. Kinsbourne indicate that the medical records now cited by petitioner were relevant to his opinion that M.L. might have been experiencing ongoing inflammation and loss of oxygen. Thus, petitioner appears to be disputing the testimony of her own expert. The second problem with petitioner’s reliance on the medical records is, as reflected in the special master’s decision, the symptoms she associates with inflammation and loss of oxygen resolved by the time that M.L. was discharged from the hospital on April 16, 2005. And, petitioner cites no medical records after this initial discharge that reflect these symptoms, i.e., high fever, cyanosis of the lips, swelling of the lips, mouth, tongue, and throat, stridor, and shortness of breath. Accordingly, the medical records are bereft of any

³¹ A third difficulty is petitioner’s attempt to introduce new evidence into the record on review. For example, in footnote 18 of her memorandum in support of her motion for review, she cites to an article to explain the significance of the severity and duration of a hypoxic-ischemic event. This article is not in the record. And, in footnote 19 of her memorandum, she explains, without citation, the significance of certain test results. There is nothing in the record supporting her explanation—no medical records, expert opinion, or medical literature. The court cannot and will not consider new evidence when determining whether a special master’s decision is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

evidence that M.L. experienced ongoing inflammation and loss of oxygen after his initial anaphylactic reaction.

In addition to referencing the medical records to demonstrate the existence of inflammation and edema-induced loss of oxygen, petitioner relies on her affidavit to supply supporting evidence. Before turning to the substance of petitioner's affidavit, however, the court is compelled to address the special master's failure to discuss the affidavit's contents in any detail.

As explained above, the record contains both an unsigned narrative prepared by petitioner and an affidavit executed by petitioner that was derived from the narrative. In these two documents, petitioner recounts M.L.'s prevaccination medical history and the events that occurred on and after April 14, 2005. The special master only briefly discussed the substance of these documents; without citing either petitioner's narrative or affidavit, he noted that (1) petitioner's description of M.L.'s wheezing, pallor, and limpness was not reflected in the medical records and (2) petitioner's purported statement that M.L.'s anaphylactic reaction occurred within four hours of his vaccinations conflicted with the medical records.³² These two comments appear to be the basis for his conclusion, later in the decision, that there were factual discrepancies between petitioner's version of events and the medical records. Otherwise, with respect to petitioner's narrative, he only noted that it had not been made part of the record before the hearing and described it as unsigned and untested. And, he mentioned the affidavit only twice, both times just to remark that it was in the record.

The court is troubled by the special master's treatment of petitioner's account of the events that affected her, her husband, and M.L. It is obvious that the special master completely

³² Contrary to the special master's averment, petitioner never stated that M.L.'s anaphylactic reaction began within four hours after his vaccinations. Rather, in her narrative, petitioner indicated that the family had gone to the mall after the visit to the pediatrician's office, where they had lunch and walked around, and upon returning home, she noticed that M.L. had goose bumps and cold skin. Then at about 3:00 p.m., an hour earlier than usual, M.L. woke up from his nap screaming and with a high fever. And, in her affidavit, petitioner stated that M.L. developed goose bumps and cold skin a few hours after his vaccinations, and then woke up from his nap at 3:00 p.m. screaming and with a high fever. In neither document did she mention the time of M.L.'s vaccinations.

It appears that the special master's misstatement is derived from the hearing transcript. During the hearing, the special master asked Dr. Kinsbourne where he obtained the information "to support the onset of the anaphylaxis in four hours," and Dr. Kinsbourne responded that he drew the information from petitioner's statement that M.L. was vaccinated at 12:00 p.m. (after the 10:30 a.m. appointment was delayed) and began to show hives at 1:00 p.m. These times do not appear in petitioner's narrative or affidavit, and it is unclear where Dr. Kinsbourne found them.

discounted petitioner's version of events—he only mentions, without elaboration, that her descriptions of wheezing, pallor, and limpness were not set forth in the medical records and that the time of the onset of M.L.'s anaphylactic reaction that she purportedly provided was in conflict with the onset time contained in the medical records. Yet the absence of the three symptoms from the medical records and the conflicting onset time do not, by themselves, render the entirety of petitioner's account unreliable or irrelevant. With respect to the three symptoms, petitioner stated that she observed them during the night following M.L.'s vaccinations, and before she took M.L. to the pediatrician the following morning. Thus, the symptoms' absence from the medical records could be explained by (1) petitioner's failure to recount to the pediatrician everything that happened during the previous night,³³ (2) the pediatrician's failure to document everything that petitioner told him, (3) petitioner's faulty recollection of the events at the time that she prepared her narrative, or (4) petitioner purposely recounting symptoms that did not exist. And, with respect to the onset time, petitioner noted that M.L. developed goose bumps and cold skin a few hours after his vaccinations, followed by screaming and a high fever at approximately 3:00 p.m., while the medical records closest in time to the vaccinations reflect that M.L.'s reaction began at 4:00 p.m. This apparent conflict in the time of onset could be explained by (1) petitioner's failure to recount to the pediatrician everything that happened during the previous twenty-four hours, (2) petitioner not realizing that the goose bumps or cold skin was related to the subsequent screaming and high fever, (3) the pediatrician's failure to document everything that petitioner told him, (4) petitioner's faulty recollection of the timing of events at the time that she prepared her narrative, or (5) petitioner purposely recounting symptoms that did not exist. The special master did not explore any of these possibilities when he remarked on the apparent discrepancies in the record.

Moreover, the special master did not explain why his decision not to credit petitioner's recollection of the three symptoms or the time of onset rendered petitioner's remaining statements unreliable or irrelevant. He described the narrative as unsigned and untested, but did not explain how, or to what extent, those characteristics rendered the narrative unreliable. Similarly, he failed to explain why he decided not to discuss the contents of petitioner's affidavit, which, unlike the narrative, was both signed and sworn.³⁴ Certainly, a fact finder is entitled to

³³ Given that petitioner had just endured a sleepless, and undoubtedly terrifying, night caring for a child experiencing an anaphylactic reaction, and that M.L.'s condition was serious enough to cause the pediatrician to call for an ambulance, it would not surprise the court if she did not recall, or recount to the pediatrician, each and every symptom that she observed. Although “[m]edical records, in general, warrant consideration as trustworthy evidence,” Cucuras v. Sec’y of HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993), there are perfectly valid reasons why they may not be complete.

³⁴ Indeed, petitioner's affidavit bears indicia of reliability. For one, it is, for the most part, consistent with the medical records. In addition, less than a year had passed between M.L.'s April 14, 2005 vaccinations and the preparation of the narrative from which the affidavit was derived (as noted above, the narrative was written by petitioner no later than March 27, 2006, the

make determinations concerning the relevance and reliability of the evidence in the record. However, in this case, the special master merely insinuated that petitioner's statements were irrelevant or unreliable—both by commenting that the narrative was unsigned and untested and by indicating that he sought in-person testimony from petitioner but that petitioner declined to offer it—and did not clearly explain the basis for refusing to consider them.³⁵

The special master's insinuations strongly imply that he found petitioner's narrative, and the affidavit derived from that narrative, not credible. If the special master truly believed that there were irreconcilable problems with petitioner's written version of events and that petitioner's testimony was necessary for him to render his decision, it was incumbent on him to compel her testimony. As reflected in the Vaccine Act, Congress intended special masters to play an inquisitorial role in Vaccine Act proceedings. See 42 U.S.C. § 300aa–12(d)(3); accord H.R. Rep. No. 101–386, at 87 (1989) (Conf. Rep.). In fulfilling that role, special masters “must consider all relevant and reliable evidence,” and may, if necessary, direct the issuance of a subpoena to require a witness's attendance at a hearing to receive that evidence. See Vaccine Rule 8. Thus, the special master could have obtained the testimony he desired. He just chose not to do so. It was not error for the special master to decline to compel petitioner's testimony, but in light of his decision, petitioner's failure to testify cannot be held against her. Therefore, the special master's insinuations that petitioner's version of events was not credible do not carry much weight.

Dr. Kinsbourne unquestionably relied upon some of petitioner's written statements in rendering his opinion. Accordingly, the special master's failure to identify and discuss the statements relied upon by Dr. Kinsbourne that were in conflict with the medical records and the special master's failure to address how those conflicts affected his decision to discount the entirety of petitioner's narrative and affidavit was an abuse of discretion.

However, the special master's failure to discuss petitioner's version of events amounts to harmless error, because it is petitioner's position—restated at oral argument—that “the medical records alone show direct clinical evidence of hypoxia and inflammation of prolonged duration,” Mot. 35, and that “the medical records alone provide support for two of Dr. Kinsbourne's

date her counsel received it). Petitioner was not recounting events that had occurred years or decades in the past.

³⁵ Petitioner's counsel must accept some responsibility. Counsel provided petitioner's expert with a document that was not part of the record before the court. And, when the expert very reasonably relied on the document in rendering his opinion, counsel did not file that document in conjunction with the expert's report, or at any time before the hearing, thus depriving respondent and its expert from considering the same information.

biological mechanisms,” *id.* at 36.³⁶ If petitioner declines to rely on her statements to support the existence of a logical sequence of cause and effect, then the special master’s failure to consider those statements is moot.

Petitioner’s argument regarding the Althen test’s second prong is premised on her assertion that she submitted evidence, ignored by the special master, demonstrating the existence of ongoing inflammation and edema-induced loss of oxygen arising from M.L.’s anaphylactic reaction. However, as discussed above, petitioner’s evidence does not reflect such persistent, subclinical processes—even Dr. Kinsbourne admitted that there was no support for them in the medical records. Indeed, as noted by the special master, Dr. MacDonald provided unrebutted testimony that if M.L.’s anaphylactic reaction was severe enough to cause brain damage, the damage would have been reflected in M.L.’s test results and clinical symptoms. Thus, there is a break in the logical sequence of cause and effect that would link the DTaP-caused anaphylactic reaction to M.L.’s focal brain injury and associated neurological problems. Without this link, petitioner cannot satisfy the second prong of the Althen test.

Petitioner attempts to avoid this outcome in two ways. First, she claims that M.L.’s abnormal EEGs reveal a focal brain injury, verifying the fact that M.L. experienced edema-induced loss of oxygen on the tissue level that affected his brain. The special master discussed the abnormal EEG results at length in his decision. He recounted Dr. MacDonald’s testimony that M.L.’s EEGs were mildly abnormal and that if M.L. suffered permanent brain damage, the EEGs would be diffusely and grossly abnormal. The special master credited Dr. MacDonald’s testimony about the EEGs over that of Dr. Kinsbourne due to extent of Dr. MacDonald’s experience in reading EEGs. The special master concluded:

What was left not addressed [by petitioner] is the critical issue linked to the medical theory of this case, that is signs on the EEG of diffuse brain damage which would support the permanent brain damage petitioner is alleging. Dr. MacDonald did not see such damage, the treating doctors did not discuss such damage and Dr. Kinsbourne, whose qualifications to read EEGs is questionable,

³⁶ Petitioner argues that even though the medical records provide “direct clinical evidence” of two of the biological mechanisms proposed by Dr. Kinsbourne, the special master improperly heightened her burden by asking for “specific proof” that the biological mechanisms were at work in M.L. Mot. 29. Petitioner misconstrues the special master’s decision. In Moberly, the Federal Circuit held that the special master did not err in concluding that the proposed theory did not support the petitioner’s claim of causation because the petitioner’s expert—Dr. Kinsbourne—conceded that there was no evidence in the record demonstrating that his proposed biological mechanisms were at work in the injured child. 592 F.3d at 1324. The special master in this case was merely applying the same standard approved in Moberly by requiring some evidence that one of the proposed biological mechanisms was at work in M.L. Nowhere did the special master require specific proof.

did not testify to such damage, and petitioner did not produce further evidence of such damage.

La Londe, 2012 WL 5351164, at *19. The court finds no error in the special master's analysis and conclusion; as he was entitled to do, he considered the testimony of both experts regarding the EEGs, found the testimony of one expert to be more persuasive, and addressed the lack of other evidence supporting petitioner's interpretation of the EEGs. Accordingly, petitioner's reliance on the abnormal EEGs to support the existence of a focal brain injury caused by a loss of oxygen related to M.L.'s anaphylactic reaction cannot stand.

Petitioner then argues that she showed a logical sequence of cause and effect because M.L. was developing normally prior to his April 14, 2005 vaccinations, after those vaccinations he suffered from an abrupt loss of speech, all of M.L.'s health care providers attributed M.L.'s neurological symptoms to his vaccinations, and none of M.L.'s health care providers identified another cause for his injuries. This argument lacks merit for at least two reasons. First, the timing of M.L.'s speech problems reveals a temporal relationship with the vaccinations, but a temporal relationship is not sufficient to establish causation. Althen, 418 F.3d at 1278. Second, most of the health care providers' medical records cited by petitioner merely note that M.L. experienced an anaphylactic reaction after his vaccinations; while some of these providers explicitly linked the anaphylactic reaction to the vaccinations, they did not link the vaccinations to M.L.'s neurological problems. Indeed, only a few of the cited records could be construed to contain a link between M.L.'s neurological problems and his vaccinations: an April 19, 2005 progress note listing an impression of questionable clinical seizures, viral syndrome, and vaccine adverse reaction; Dr. Tan's April 20, 2005 notation that he could not "rule out the possibility that this seizure could be related to a reaction to the vaccines at this time versus primary epilepsy"; Dr. Cheas's May 5, 2005 notation that he questioned whether M.L.'s signs, symptoms, or condition was related to his vaccinations; a speech therapist's December 2005 notation that M.L.'s history included anaphylactic shock with seizures caused by his vaccinations; and a physical therapist's note from July 2007 that M.L. suffered from a "vaccine injury in April 2005." The progress note does not suggest that M.L.'s vaccinations caused his seizures, Dr. Tan's note suggests possible causation but also suggests an alternative cause, Dr. Cheas's note only questions whether there is a link; the speech therapist was only recounting M.L.'s history and was not rendering a diagnosis; and the physical therapist's note was made over two years after the injury and reflects her report of M.L.'s history, not her diagnosis. None of these records contains a definitive opinion that M.L.'s neurological problems were caused by his vaccinations. Thus, although the opinion of treating physicians can be probative, Capizzano, 440 F.3d at 1326, the records cited by petitioner cannot establish causation.³⁷

³⁷ Three other records—not cited by petitioner in support of this argument—suggest a causative link: the VAERS report submitted by Dr. Cheas, an April 21, 2005 progress note, and the letter describing Dr. Davis's June 16, 2010 evaluation of M.L. The submission of a VAERS report, however, does not necessarily indicate that the reporting individual believes that there is a causative link between the administered vaccine and the subsequent adverse event. See Pet'r Ex.

In sum, the special master's conclusion that petitioner failed to satisfy the second prong of the Althen test by a preponderance of the evidence was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

4. Althen Prong Three

Petitioner contends that she satisfied the third prong of the Althen test, which "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The special master agreed with petitioner, holding that there was a clear temporal relationship between M.L.'s April 14, 2005 vaccinations and his subsequent seizures and lack of speech.³⁸ However, although probative, satisfaction of the third prong is insufficient, standing alone, to prove causation. Althen, 418 F.3d at 1278. Petitioner did not satisfy the first two prongs of the Althen test. Thus, petitioner failed to prove that the April 14, 2005 vaccinations actually caused M.L.'s injuries.

B. Expert Credibility

Petitioner's failure to establish that the special master erred in concluding that she had not proven causation-in-fact is fatal to her motion for review. Nevertheless, the court will briefly address petitioner's remaining two objections to the special master's decision. The first of these remaining objections is that the special master improperly used a credibility determination of her expert to shield his decision on causation.

4 at 81 ("FDA and CDC encourage patients, parents, and others to report any significant problems experienced after vaccination, even if they are not certain that a vaccine caused them."). And, the April 21, 2005 progress note suggests a possible link between the vaccinations and M.L.'s seizures, but also suggests that the seizures might be idiopathic. Finally, although Dr. Davis definitively opines that M.L.'s neurological injuries were the result of his anaphylactic reaction, it is not apparent that he had access to M.L.'s complete body of medical records in formulating his opinion. Thus, none of these records establishes causation.

³⁸ Elsewhere in her memorandum in support of her motion for review, petitioner complains that "[t]he special master clearly, and inappropriately, placed great significance on" the notation from M.L.'s fifteen-month well-child examination that M.L. "[did not] want to talk." Mot. 45. However, the special master only mentions this notation in conjunction with his analysis of the third prong of the Althen test, which the special master concluded had been satisfied by petitioner. Thus, to the extent that the special master placed any weight at all on the notation, he ultimately determined that it was not significant enough to weigh against a finding of a temporal relationship.

In Andreu, the Federal Circuit remarked: “While considerable deference must be accorded to the credibility determinations of special masters, this does not mean that a special master can cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review.” 569 F.3d at 1379 (citation omitted). The Federal Circuit expanded on its remarks in Andreu in subsequent decisions:

In Moberly, we reiterated that a special master may not cloak the application of an erroneous legal standard in the guise of a credibility determination to shield it from appellate review. We went on to clarify that this does not mean that “a special master, as the finder of fact in a Vaccine Act case, is prohibited from making credibility determinations regarding expert testimony.” We indicated that “[a]ssessments as to the reliability of expert testimony often turn on credibility determinations” and “[f]inders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.” Our discussion of the issue in Broekelschen is equally clear. In that case, we recognized that “[e]xpert medical testimony is often very important in Vaccine Act cases based on off-Table injuries requiring proof of actual causation.” We again explained that “the special master’s decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories” and such credibility findings “are virtually unchallengeable on appeal.” Finally, in Doe,³⁹ we upheld a special master’s factual findings as not arbitrary and capricious “particularly in light of the credibility findings made as to the parties’ respective experts.” We found no basis for disturbing the special master’s credibility findings as to those experts, and again emphasized that “the special master’s unique position to see the witnesses and hear their testimony” makes “such credibility assessments . . . ‘virtually unreviewable on appeal.’”

Porter v. Sec’y of HHS, 663 F.3d 1242, 1250-51 (Fed. Cir. 2011) (footnote added) (citations omitted).

In his decision, the special master criticized Dr. Kinsbourne’s testimony as suffering from “extreme deficits,” specifically remarking:

The testimony in this case was as poor as any the undersigned has experienced in twenty years. Dr. Kinsbourne’s testimony highlighted his willingness to testify in a case where he proffered a theory that he conceded he has never seen before, he went to the literature and could not find specific support for, and he did not completely understand. Further, in applying his theory to the facts of this case there is no support in the medical records that the events transpired as he proposed.

³⁹ Doe 11 v. Sec’y of HHS, 601 F.3d 1349 (Fed. Cir. 2010).

. . . While the undersigned does not blame Dr. Kinsbourne for petitioner's counsel's decision not to file the mother's narrative that does not discharge him of his obligation as a medical expert to provide reliable support for his medical opinion. An expert should not blindly accept the statements of parents, but must reconcile such statements with the medical records. In this matter, Dr. Kinsbourne stated that the mother's narrative did not conflict with his read of the medical records. Yet from the beginning it became clear that Dr. Kinsbourne failed to look at the medical records [on] at least one occasion. Dr. Kinsbourne relied on the mother's statement that M.L. suffered an anaphylactic reaction within four hours of vaccination The medical records clearly state otherwise and Dr. Kinsbourne himself acknowledged that he should have considered various notations regarding the timing of M.L.'s vaccination. This lack of review of the records, in conjunction with the many other deficiencies in Dr. Kinsbourne's theory seriously undermines his credibility. There exists a serious question as to whether Dr. Kinsbourne should be paid for his efforts.

Petitioner's theory must meet the three prongs of laid out in Althen. Dr. Kinsbourne attempts to lay out a medical theory causally connecting the vaccination to the injury. Unfortunately for petitioner this theory fails to pass any reasonable test of reliability. Dr. Kinsbourne has testified as a medical expert in the Program for many years with varying degrees of success. In this case, Dr. Kinsbourne speculates to a theory which addresses the unique sequence of events in M.L.'s case in an effort to try to fill in the causative blanks and link M.L.'s injuries to his vaccination. Dr. Kinsbourne himself, is unable to specifically explain or opine to any of the three mechanisms he proposes as causing M.L.'s brain damage. This is not reliable testimony.

La Londe, 2012 WL 5351164, at *17-18 (footnote and citations omitted).

To rebut this passage from the special master's decision, petitioner first asserts that Dr. Kinsbourne "epitomizes the standard of excellence that petitioners' expert require to assist special masters" and cites a number of decisions in which Dr. Kinsbourne was praised.⁴⁰ However, the quality of the reports and testimony that Dr. Kinsbourne provided in other cases cannot be used as a proxy for the quality of the reports and testimony that he provided in this case. Nor can a flawed expert opinion be rehabilitated merely because the expert has testified successfully in prior cases. While the existence of prior successful testimony may lend credence and enhance an expert's reputation, it cannot provide the justification for a special master to ignore expert opinion—oral or written—if that opinion is incoherent, illogical, inconsistent, or incorrect. Consequently, it was not error for the special master to consider only the opinion

⁴⁰ As respondent notes, petitioner omitted citations to a number of more recent decisions in which Dr. Kinsbourne's reports or testimony was criticized.

provided by Dr. Kinsbourne in this case. In addition, in emphasizing the excellence of Dr. Kinsbourne's credentials, petitioner mistakenly conflates the credibility of Dr. Kinsbourne's testimony with the credibility of Dr. Kinsbourne personally. The special master's focus was solely on the former, and not on the latter. As Federal Circuit precedent makes clear, the special master properly evaluated the credibility of Dr. Kinsbourne's testimony.

Petitioner next asserts that the special master should not criticize Dr. Kinsbourne for relying on statements by petitioner because the special master himself ignored all of petitioner's statements in his decision. As noted above, the court concluded that the special master erred in his treatment of petitioner's narrative and affidavit. However, the special master's errors do not preclude him from criticizing Dr. Kinsbourne if that criticism is valid. And while some of the special master's comments may sound harsh, he supports his criticism of Dr. Kinsbourne's testimony with specific examples and evidence from the record.⁴¹

In addition, petitioner contends that the special master's discussion of Dr. Kinsbourne's credibility was meant to disguise the fact that the special master ignored important facts found in the medical records and failed to discuss any of the filed medical literature. Most of the medical records that petitioner claims were ignored by the special master relate to the timing of the onset of M.L.'s initial anaphylactic reaction. However, the precise timing of the initial reaction is not relevant because the parties agreed that the reaction was caused by the DTaP vaccine. Moreover, the evidence regarding the precise time of onset was offered in support of petitioner's claim that M.L. suffered from a Table injury, and petitioner has not challenged the special master's rejection of her Table claim in her motion for review. Petitioner also decries the special master's failure to discuss the cyanosis observed and reported by the EMS personnel on April 15, 2005, but, as noted above, Dr. Kinsbourne did not rely on this symptom as evidence of ongoing inflammation or edema-induced loss of oxygen.

With respect to the medical literature, the record includes (1) two articles relating to reactions associated with the DTaP vaccine; (2) a textbook excerpt containing an explanation of two-phase anaphylactic reactions and an article relating to urticaria and angioedema, both attached to Dr. Kinsbourne's report; (3) an article concerning T-cell immune responses induced by acellular pertussis vaccines in mice; (4) an article concerning cytokine induction following the administration of acellular pertussis vaccines; (5) nine articles related to language development and brain injuries, all attached to Dr. Kinsbourne's supplemental report; (6) seven articles concerning vaccines, anaphylaxis, and hypotonic-hyporesponsive episodes, all attached to Dr. MacDonald's report; and (7) four articles related to language development and brain injuries, all

⁴¹ As the court noted above, the special master erroneously attributed an onset time (within four hours postvaccination) to petitioner, rather than to Dr. Kinsbourne's representation of what petitioner said. Nevertheless, the special master's criticism that Dr. Kinsbourne did not compare the onset time purportedly offered by petitioner to the onset time that appeared in the medical records remains valid.

attached to Dr. MacDonald's supplemental report.⁴² The special master addressed the literature attached to Dr. Kinsbourne's initial report and noted the absence of literature supporting Dr. Kinsbourne's theory of causation, but did not discuss the substance of the remaining literature in the record.

Generally, the court presumes that a special master has reviewed all of the material in the record, regardless of whether it is mentioned in his or her decision. Hazlehurst v. Sec'y of HHS, 604 F.3d 1343, 1352 (Fed. Cir. 2010). Nevertheless, petitioner finds fault with the special master's failure to discuss some of the literature, specifically mentioning the literature related to hypotonic-hyporesponsive episodes and the literature related to language development and brain injuries. As noted above, the literature related to hypotonic-hyporesponsive episodes is irrelevant because Dr. Kinsbourne's theory of causation did not involve a hypotonic-hyporesponsive episode. And, as explained in more detail below, literature related to whether problems with language development can be associated with damage to a particular area of the brain is irrelevant because petitioner was unable to establish either that an anaphylactic reaction could cause a focal brain injury or that M.L. experienced ongoing inflammation or edema-induced loss of oxygen due to his anaphylactic reaction that caused a focal brain injury. In other words, literature concerning the manifestations of a focal brain injury is of no use when it has not been established that a vaccine could cause or did cause the focal brain injury. Accordingly, the special master's failure to discuss the literature cited by petitioner does not constitute error.

In sum, the court concludes that the special master did not, as petitioner claims, cloak his decision on causation-in-fact with an assault on Dr. Kinsbourne's credibility. While the special master may not have had kind words about the quality of Dr. Kinsbourne's testimony, his comments were directed at the reliability of the expert witness's testimony and he substantively supported his criticism with evidence from the record. His discussion of Dr. Kinsbourne's credibility and how that credibility affected Dr. Kinsbourne's theory of causation was therefore not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

C. Evidence of Neurological Injuries

Petitioner's final remaining objection is that the special master erred by failing to evaluate the evidence related to M.L.'s speech problems. As the discussion above reflects, this argument can be disposed of without much difficulty.

The special master concluded that petitioner was unable to satisfy the first two prongs of the Althen test. In particular, he concluded that petitioner had not established that an anaphylactic reaction could cause a focal brain injury, as required under the first prong. And, the special master concluded that petitioner had not established that M.L. experienced ongoing inflammation or edema-induced loss of oxygen due to his anaphylactic reaction that caused a

⁴² This literature is designated Petitioner's Exhibits 16-17, 20 tabs A-B, 53-54, 56 tabs A-I, and Respondent's Exhibits C-I, K-N.

focal brain injury, as required under the second prong. In other words, petitioner was not able to demonstrate that M.L.'s DTaP vaccination and resulting anaphylactic reaction could cause or did cause a focal brain injury. The court found no error in these conclusions.

Because he found that petitioner had not satisfied the Althen standards for proving causation-in-fact, the special master concluded that it was unnecessary "to resolve the continued disagreements regarding the aphasia and associated findings on [the] EEG[s]." La Londe, 2012 WL 5351164, at *19. He was correct. An analysis of whether the abnormalities depicted on M.L.'s EEGs were associated with M.L.'s speech problems would not have cured the underlying problem in petitioner's case: her inability to establish in the first instance that M.L.'s anaphylactic reaction could have and did cause a focal brain injury. Thus, even if M.L. (1) experienced a focal brain injury (2) that was reflected on the EEGs (3) and was manifested by speech difficulties, petitioner could not link any of it to M.L.'s anaphylactic reaction. Accordingly, the court concludes that the special master's decision not to evaluate evidence related to M.L.'s speech problems was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

III. CONCLUSION

For the reasons stated above, the court **DENIES** petitioner's motion for review and **SUSTAINS** the decision of the special master. The clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Margaret M. Sweeney
MARGARET M. SWEENEY
Judge